



Agency for Healthcare Research and Quality
Advancing Excellence in Health Care



NATIONAL
GUIDELINE
CLEARINGHOUSE

General

Guideline Title

Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement.

Bibliographic Source(s)

U.S. Preventive Services Task Force. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2012 Jul 17;157(2):120-34. [64 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: U.S. Preventive Services Task Force. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2008 Aug 5;149(3):185-91. [19 references]

Recommendations

Major Recommendations

The US Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the Levels of Certainty regarding Net Benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendation and Evidence

The USPSTF recommends against prostate-specific antigen (PSA)-based screening for prostate cancer. This is a grade D recommendation.

Clinical Considerations

Although the USPSTF discourages the use of screening tests for which the benefits do not outweigh the harms in the target population, it recognizes the common use of PSA screening in practice today and understands that some men will continue to request screening and some physicians will continue to offer it. The decision to initiate or continue PSA screening should reflect an explicit understanding of the possible benefits and harms and respect the patients' preferences. Physicians should not offer or order PSA screening unless they are prepared to engage in shared decision making that enables an informed choice by patients. Similarly, patients requesting PSA screening should be provided with the opportunity to make informed choices to be screened that reflect their values about specific benefits and harms. Community- and employer-based screening should be discontinued. Table 3 in the original guideline document presents reasonable estimates of the likely outcomes of screening, given the current approach to screening and treatment of screen-detected prostate cancer in the United States.

The treatment of some cases of clinically localized prostate cancer can change the natural history of the disease and may reduce morbidity and mortality in a small percentage of men, although the prognosis for clinically localized cancer is generally good regardless of the method of detection,

even in the absence of treatment. The primary goal of PSA-based screening is to find men for whom treatment would reduce morbidity and mortality. Studies demonstrate that the number of men who experience this benefit is, at most, very small, and PSA-based screening as currently implemented in the United States produces more harms than benefits in the screened population. It is not known whether an alternative approach to screening and management of screen-detected disease could achieve the same or greater benefits while reducing the harms. Focusing screening on men at increased risk for prostate cancer mortality may improve the balance of benefits and harms, but existing studies do not allow conclusions about a greater absolute or relative benefit from screening in these populations. Lengthening the interval between screening tests may reduce harms without affecting cancer mortality; the only screening trial that demonstrated a prostate cancer–specific mortality benefit generally used a 2- to 4-year screening interval. Other potential ways to reduce diagnostic- and treatment-related harms include increasing the PSA threshold used to trigger the decision for biopsy or need for treatment, or reducing the number of men having active treatment at the time of diagnosis through watchful waiting or active surveillance. Periodic digital rectal examinations could also be an alternative strategy worthy of further study. In the only randomized trial demonstrating a mortality reduction from radical prostatectomy for clinically localized cancer, a high percentage of men had palpable cancer. All of these approaches require additional research to better elucidate their merits and pitfalls and more clearly define an approach to the diagnosis and management of prostate cancer that optimizes the benefits while minimizing the harms.

Patient Population under Consideration

This recommendation applies to men in the general U.S. population. Older age is the strongest risk factor for the development of prostate cancer. However, neither screening nor treatment trials show benefit in men older than 70 years. Across age ranges, black men and men with a family history of prostate cancer have an increased risk of developing and dying of prostate cancer. Black men are approximately twice as likely to die of prostate cancer than other men in the United States, and the reason for this disparity is unknown. Black men represented a small minority of participants in the randomized clinical trials of screening (4% of enrolled men in the PLCO [Prostate, Lung, Colorectal, and Ovarian Cancer] trial were non-Hispanic black; although the ERSPC [European Randomized Study of Screening for Prostate Cancer] and other trials did not report the specific racial demographic characteristics of participants, they likely were predominately white). Thus, no firm conclusions can be made about the balance of benefits and harms of PSA-based screening in this population. However, it is problematic to selectively recommend PSA-based screening for black men in the absence of data that support a more favorable balance of risks and benefits. A higher incidence of cancer will result in more diagnoses and treatments, but the increase may not be accompanied by a larger absolute reduction in mortality. Preliminary results from PIVOT (Prostate Cancer Intervention Versus Observation Trial), in which 30% of enrollees were black, have become available since the publication of the USPSTF's commissioned evidence reviews. Investigators found no difference in outcomes due to treatment of prostate cancer in black men compared with white men.

Exposure to Agent Orange (a defoliant used in the Vietnam War) is considered to be a risk factor for prostate cancer, although few data exist on the outcomes or effect of PSA testing and treatment in these persons. Prostate cancer in Vietnam veterans who were exposed to Agent Orange is considered a service-connected condition by the Veterans Health Administration. The USPSTF did not evaluate the use of the PSA test as part of a diagnostic strategy in men with symptoms potentially suggestive of prostate cancer. However, the presence of urinary symptoms was not an inclusion or exclusion criterion in screening or treatment trials, and approximately one quarter of men in screening trials had bothersome lower urinary tract symptoms (nocturia, urgency, frequency, and poor stream). The presence of benign prostatic hyperplasia is not an established risk factor for prostate cancer, and the risk for prostate cancer among men with elevated PSA levels is lower in men with urinary symptoms than in men without symptoms. This recommendation also does not include the use of the PSA test for surveillance after diagnosis or treatment of prostate cancer and does not consider PSA-based testing in men with known BRCA gene mutations who may be at increased risk for prostate cancer.

Screening Tests

Prostate-specific antigen–based screening in men aged 50 to 74 years has been evaluated in 5 unique randomized, controlled trials of single or interval PSA testing with various PSA cutoffs and screening intervals, along with other screening methods, such as digital rectal examination or transrectal ultrasonography. Screening tests or programs that do not incorporate PSA testing, including digital rectal examination alone, have not been adequately evaluated in controlled studies.

The PLCO trial found a nonstatistically significant increase in prostate cancer mortality in the annual screening group at 11.5 and 13 years, with results consistently favoring the usual care group.

A prespecified subgroup analysis of men aged 55 to 69 years in the ERSPC trial demonstrated a prostate cancer mortality rate ratio (RR) of 0.80 (95% confidence interval [CI], 0.65 to 0.98) in screened men after a median follow-up of 9 years, with similar findings at 11 years (RR, 0.79 [CI, 0.68 to 0.91]). Of the 7 centers included in the ERSPC analysis, only 2 countries (Sweden and the Netherlands) reported statistically significant reductions in prostate cancer mortality after 11 years (5 did not), and these results seem to drive the overall benefit found in this trial (see Figure 2 in the original guideline document). No study reported any factors, including patient age, adherence to site or study protocol, length of follow-up, PSA thresholds, or intervals between tests, that could clearly explain why mortality reductions were larger in Sweden or the Netherlands than in other European countries or the United States (PLCO trial). Combining the results through meta-analysis may be inappropriate due to clinical and

methodological differences across trials.

No study found a difference in overall or all-cause mortality. This probably reflects the high rates of competing mortality in this age group, because these men are more likely to die of prostate cancer, as well as the limited power of prostate cancer screening trials to detect differences in all-cause mortality, should they exist. Even in the "core" age group of 55 to 69 years in the ERSPC trial, only 462 of 17,256 deaths were due to prostate cancer. The all-cause mortality RR was 1.00 (CI, 0.98 to 1.02) in all men randomly assigned to screening versus no screening. Results were similar in men aged 55 to 69 years. The absence of any trend toward a reduction in all-cause mortality is particularly important in the context of the difficulty of attributing death to a specific cause in this age group.

Treatment

Primary management strategies for PSA-detected prostate cancer include watchful waiting (observation and physical examination with palliative treatment of symptoms), active surveillance (periodic monitoring with PSA tests, physical examinations, and repeated prostate biopsy) with conversion to potentially curative treatment at the sign of disease progression or worsening prognosis, and surgery or radiation therapy. There is no consensus about the optimal treatment of localized disease. From 1986 through 2005, PSA-based screening likely resulted in approximately 1 million additional U.S. men being treated with surgery, radiation therapy, or both compared with the time before the test was introduced.

At the time of the USPSTF's commissioned evidence review, only 1 recent randomized, controlled trial of surgical treatment versus observation for clinically localized prostate cancer was available. In the Scandinavian Prostate Cancer Group Study 4 trial, surgical management of localized, primarily clinically detected prostate cancer was associated with an approximate 6% absolute reduction in prostate cancer and all-cause mortality at 12 to 15 years of follow-up; benefit seemed to be limited to men younger than 65 years. Subsequently, preliminary results were reported from another randomized trial that compared external beam radiotherapy (EBRT) with watchful waiting in 214 men with localized prostate cancer detected before initiation of PSA screening. At 20 years, survival did not differ between men randomly assigned to watchful waiting or EBRT (31% vs. 35%; $P = 0.26$). Prostate cancer mortality at 15 years was high in each group but did not differ between groups (23% vs. 19%; $P = 0.51$). External beam radiotherapy did reduce distant progression and recurrence-free survival. In men with localized prostate cancer detected in the early PSA screening era, preliminary findings from PIVOT show that, after 12 years, intention to treat with radical prostatectomy did not reduce disease-specific or all-cause mortality compared with observation; absolute differences were less than 3% and not statistically different. An ongoing trial in the United Kingdom (ProtecT [Prostate Testing for Cancer and Treatment]) comparing radical prostatectomy with EBRT or active surveillance has enrolled nearly 2000 men with PSA-detected prostate cancer. Results are expected in 2015.

Up to 0.5% of men will die within 30 days of having radical prostatectomy, and 3% to 7% will have serious surgical complications. Compared with men who choose watchful waiting, an additional 20% to 30% or more of men treated with radical prostatectomy will experience erectile dysfunction, urinary incontinence, or both after 1 to 10 years. Radiation therapy is also associated with increases in erectile, bowel, and bladder dysfunction.

Definitions:

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	<i>Note: The following statement is undergoing revision.</i> Clinicians may provide this service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit from this service.	Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and

Grade	Grade Definitions	harms.	Suggestions for Practice
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USPSTF Levels of Certainty Regarding Net Benefit

Definition: The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:</p> <ul style="list-style-type: none"> • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>
Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes <p>More information may allow an estimation of effects on health outcomes.</p>

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Prostate cancer

Guideline Category

Prevention

Screening

Clinical Specialty

Family Practice

Internal Medicine

Oncology

Preventive Medicine

Urology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendations and supporting scientific evidence on screening for prostate cancer
- To update the 2008 USPSTF recommendations on screening for prostate cancer

Target Population

Adolescent and adult men in the general U.S. population

Interventions and Practices Considered

Screening for prostate cancer using the prostate-specific antigen (PSA) test

Major Outcomes Considered

Key Question 1: Does prostate-specific antigen (PSA)-based screening decrease prostate cancer-specific or all-cause mortality?

Key Question 2: What are the harms of PSA-based screening for prostate cancer?

Key Question 3: What are the benefits of treatment of early-stage or screening-detected prostate cancer?

Key Question 4: What are the harms of treatment of early-stage or screening-detected prostate cancer?

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): Systematic evidence reviews were prepared by the Agency for Healthcare Research and Quality (AHRQ) and the Oregon Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Sources and Searches

Reviewers searched Ovid MEDLINE from 2002 to July 2011, PubMed from 2007 to July 2011, and the Cochrane Library Database through the second quarter of 2011 and reviewed reference lists to identify relevant articles published in English.

Study Selection

At least 2 reviewers independently evaluated each study to determine inclusion eligibility. Inclusion was restricted to published studies. Reviewers included randomized trials of screening for prostate cancer in asymptomatic men (including those with chronic, mild lower urinary tract symptoms) that incorporated 1 or more prostate-specific antigen (PSA) measurements, with or without additional methods, such as digital rectal examination, and reported all-cause or prostate cancer-specific mortality or harms associated with screening. Reviewers also included randomized trials and cohort studies of men with screening-detected prostate cancer that compared radical prostatectomy or radiation therapy (the most common primary treatments for localized prostate cancer) with watchful waiting and reported all-cause mortality, prostate cancer-specific mortality, or prespecified harms (quality of life or functional status, urinary incontinence, bowel dysfunction, erectile dysfunction, psychological effects, and surgical complications). Studies of clinically localized (T1 or T2) prostate cancer were included because more than 90% of cases of screening-detected prostate cancer are localized. Reviewers included only studies that reported risk estimates for mortality adjusted at a minimum for age at diagnosis and tumor grade (no study reported adjusted risk estimates for treatment harms). Large (>1000 participants) uncontrolled observational studies of perioperative mortality and surgical complications were also included.

Reviewers classified "no treatment," "observation," or "deferred treatment" as watchful waiting because patients probably received at least watchful waiting. Watchful waiting was also grouped with active surveillance because studies of active surveillance provided insufficient information to determine whether more active follow-up actually occurred, and older studies used these terms interchangeably.

Number of Source Documents

- Effectiveness and harms of screening: 6 articles met inclusion criteria
- Effectiveness and harms of treatment:
 - Key Question 3: 2 randomized controlled trials (RCTs), 9 cohort studies
 - Key Question 4: 2 RCTs, 14 cohort studies, 6 uncontrolled studies

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

The overall strength of the body of evidence for each key question (good, fair, poor) was assessed using methods developed by the U.S. Preventive Services Task Force (USPSTF) on the basis of the number, quality, and size of studies; consistency of results between studies; and directness of evidence (described in Appendix 2 of the Evidence Synthesis; see the "Availability of Companion Documents" field).

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): Systematic evidence reviews were prepared by the Agency for Healthcare Research and Quality (AHRQ) and the Oregon Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Extraction and Quality Assessment

One investigator abstracted details on the patient population, study design, analysis, duration of follow-up, and results. A second investigator reviewed data abstraction for accuracy. Two investigators independently applied criteria developed by the USPSTF to rate the quality of each study as good, fair, or poor. Discrepancies were resolved through a consensus process.

Data Synthesis and Analysis

Reviewers assessed the aggregate internal validity (quality) of the body of evidence for each key question (good, fair, and poor) by using methods developed by the USPSTF on the basis of the number, quality, and size of studies; consistency of results between studies; and directness of evidence. Results of treatment studies were synthesized descriptively, using medians and ranges, because few randomized, controlled trials (RCTs) were available and studies varied in the populations and interventions evaluated, methodologic quality, duration of follow-up, and other factors. Results were stratified according to study type and qualitatively assessed the effects of study quality, duration of follow-up, year of publication, and mean age on results.

Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

Table 1. U.S. Preventive Services Task Force Recommendation Grid*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

*A, B, C, D, and I (Insufficient) represent the letter grades of recommendation or statement of insufficient evidence assigned by the U.S. Preventive Services Task Force after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the Task Force seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the Task Force considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)

3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist us in drawing conclusions (e.g., presence or absence of dose-response effects, fit within a biologic model)?

The next step in the Task Force process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the Task Force's overall assessment of evidence was described as good, fair, or poor. The Task Force realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the Task Force's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the Task Force makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The Task Force must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that 1 of the key questions in the analytic framework refers to the potential harms of the preventive service. The Task Force considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the Task Force assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The Task Force would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The Task Force would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see "Availability of Companion Documents" field) summarizes the current terminology used by the Task Force to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF et al., Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med.* 2007;147:871-875 [5 references].

Rating Scheme for the Strength of the Recommendations

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	<i>Note: The following statement is undergoing revision.</i> Clinicians may provide this service to selected patients depending on individual circumstances. However, for most individuals	Offer or provide this service only if other considerations support the offering or providing the service in an individual patient.

Grade	Grade Definitions	Suggestions for Practice
	without signs or symptoms there is likely to be only a small benefit from this service.	
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:</p> <ul style="list-style-type: none"> • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>
Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes <p>More information may allow an estimation of effects on health outcomes.</p>

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft systematic evidence review to 4 to 6 external experts and to federal agencies and professional and disease-based health organizations with interests in the topic. They ask the experts to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the Task Force in memo form. In this way, the Task Force can consider these external comments and a final version of the systematic review before it votes on its recommendations about the service. Draft recommendations are then circulated for comment from reviewers representing professional societies, voluntary organizations and Federal agencies, as well as posted on the Task Force Web site for public comment. These comments are discussed before the whole USPSTF before final recommendations are confirmed.

Response to Public Comment. A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 11 October to 13 December 2011. Commenters expressed concern that a grade D recommendation from the USPSTF would preclude the opportunity for discussion between men and their personal health care providers, interfere with the clinician–patient relationship, and prevent men from being able to make their own decisions about whether to be screened for prostate cancer. Some commenters asked that the USPSTF change its recommendation to a grade C to allow men to continue to make informed decisions about screening. Recommendations from the USPSTF are chosen on the basis of the risk–benefit ratio of the intervention: a grade D recommendation means that the USPSTF has concluded that there is at least moderate certainty that the harms of doing the intervention equal or outweigh the benefits in the target population, whereas a grade C recommendation means that the USPSTF has concluded that there is at least moderate certainty that the overall net benefit of the service is small. The USPSTF could not assign a grade C recommendation for prostate-specific antigen (PSA) screening because it did not conclude that the benefits outweigh the harms. In the Clinical Considerations section, the USPSTF has clarified that a D recommendation does not preclude discussions between clinicians and patients to promote informed decision making that supports personal values and preferences.

See the original guideline document for a full discussion of the USPSTF response to public comment.

Recommendations of Others. Recommendations for screening for prostate cancer from the following groups were discussed: the American Academy of Family Physicians, the American College of Physicians, the American College of Preventive Medicine, the American Cancer Society, and the American Urological Association.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is not specifically stated for each recommendation.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Benefits of Detection and Early Treatment

The primary goal of prostate cancer screening is to reduce deaths due to prostate cancer and, thus, increase length of life. An additional important outcome would be a reduction in the development of symptomatic metastatic disease. Reduction in prostate cancer mortality was the primary outcome used in available randomized, controlled trials of prostate cancer screening. Although 1 screening trial reported on the presence of metastatic disease at the time of prostate cancer diagnosis, no study reported on the effect of screening on the development of subsequent metastatic disease, making it difficult to assess the effect of lead-time bias on the reported rates.

Men with screen-detected cancer can potentially fall into 1 of 3 categories: those whose cancer will result in death despite early diagnosis and treatment, those who will have good outcomes in the absence of screening, and those for whom early diagnosis and treatment improves survival. Only randomized trials of screening allow an accurate estimate of the number of men who fall into the latter category. There is convincing evidence that the number of men who avoid dying of prostate cancer because of screening after 10 to 14 years is, at best, very small. Two major trials of prostate-specific antigen (PSA) screening were considered by the U.S. Preventive Services Task Force (USPSTF): the U.S. PLCO (Prostate, Lung, Colorectal, and Ovarian) Cancer Screening Trial and the ERSPC (European Randomized Study of Screening for Prostate Cancer). The U.S. trial did not demonstrate any prostate cancer mortality reduction. The European trial found a reduction in prostate cancer deaths of

approximately 1 death per 1000 men screened in a subgroup of men aged 55 to 69 years. This result was heavily influenced by the results of 2 countries; 5 of the 7 countries reporting results did not find a statistically significant reduction. All-cause mortality in the European trial was nearly identical in the screened and nonscreened groups.

There is adequate evidence that the benefit of PSA screening and early treatment ranges from 0 to 1 prostate cancer deaths avoided per 1000 men screened.

Potential Harms

Harms of Detection and Early Treatment

Harms Related to Screening and Diagnostic Procedures

Convincing evidence demonstrates that the prostate-specific antigen (PSA) test often produces false-positive results (approximately 80% of positive PSA test results are false-positive when cutoffs between 2.5 and 4.0 µg/L are used). There is adequate evidence that false-positive PSA test results are associated with negative psychological effects, including persistent worry about prostate cancer. Men who have a false-positive test result are more likely to have additional testing, including 1 or more biopsies, in the following year than those who have a negative test result. Over 10 years, approximately 15% to 20% of men will have a PSA test result that triggers a biopsy, depending on the PSA threshold and testing interval used. New evidence from a randomized trial of treatment of screen-detected cancer indicates that roughly one third of men who have prostate biopsy experience pain, fever, bleeding, infection, transient urinary difficulties, or other issues requiring clinician follow-up that the men consider a "moderate or major problem"; approximately 1% require hospitalization.

The U.S. Preventive Services Task Force (USPSTF) considered the magnitude of these harms associated with screening and diagnostic procedures to be at least small.

Harms Related to Treatment of Screen-Detected Cancer

Adequate evidence shows that nearly 90% of men with PSA-detected prostate cancer in the United States have early treatment with surgery, radiation, or androgen deprivation therapy. Adequate evidence shows that up to 5 in 1000 men will die within 1 month of prostate cancer surgery and between 10 and 70 men will have serious complications but survive. Radiotherapy and surgery result in long-term adverse effects, including urinary incontinence and erectile dysfunction in at least 200 to 300 of 1000 men treated with these therapies. Radiotherapy is also associated with bowel dysfunction.

Some clinicians have used androgen deprivation therapy as primary therapy for early-stage prostate cancer, particularly in older men, although this is not a U.S. Food and Drug Administration (FDA)–approved indication and it has not been shown to improve survival in localized prostate cancer. Adequate evidence shows that androgen deprivation therapy for localized prostate cancer is associated with erectile dysfunction (in approximately 400 of 1000 men treated), as well as gynecomastia and hot flashes.

There is convincing evidence that PSA-based screening leads to substantial overdiagnosis of prostate tumors. The amount of overdiagnosis of prostate cancer is of important concern because a man with cancer that would remain asymptomatic for the remainder of his life cannot benefit from screening or treatment. There is a high propensity for physicians and patients to elect to treat most cases of screen-detected cancer, given our current inability to distinguish tumors that will remain indolent from those destined to be lethal. Thus, many men are being subjected to the harms of treatment of prostate cancer that will never become symptomatic. Even for men whose screen-detected cancer would otherwise have been later identified without screening, most experience the same outcome and are, therefore, subjected to the harms of treatment for a much longer period of time. There is convincing evidence that PSA-based screening for prostate cancer results in considerable overtreatment and its associated harms.

The USPSTF considered the magnitude of these treatment-associated harms to be at least moderate.

Qualifying Statements

Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive services for patients without related signs or symptoms.
- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF

does not consider the costs of providing a service in this assessment.

- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Implementation of the Guideline

Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the Agency for Healthcare Research and Quality will make all U.S. Preventive Services Task Force (USPSTF) products available through its [Web site](#) . The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access U.S. Preventive Services Task Force materials and adapt them for their local needs. Online access to U.S. Preventive Services Task Force products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

Implementation Tools

Patient Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

U.S. Preventive Services Task Force. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2012 Jul 17;157(2):120-34. [64 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1996 (revised 2012 Jul 17)

Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the U.S. Preventive Services Task Force do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

Source(s) of Funding

United States Government

Guideline Committee

U.S. Preventive Services Task Force (USPSTF)

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**Members of the Task Force at the time this recommendation was finalized. For a list of current Task Force members, go to <http://www.uspreventiveservicestaskforce.org/Page/Name/our-members> .*

Financial Disclosures/Conflicts of Interest

The U.S. Preventive Services Task Force has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. Task Force members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: U.S. Preventive Services Task Force. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med* 2008 Aug 5;149(3):185-91. [19 references]

Guideline Availability

Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

Availability of Companion Documents

The following are available:

- Chou R, Crosswell JM, Dana T, Bougatsos C, Blazina I, Fu R, Gleitsmann K, Koenig HC, Lam C, Maltz A, Rugge JB, Lin K. Screening for Prostate Cancer: A Review of the Evidence for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2011;155:762-771.
- Lin K, Crosswell JM, Koenig H, Lam C, Maltz A. Prostate-Specific Antigen-Based Screening for Prostate Cancer: An Evidence Update for the U.S. Preventive Services Task Force. Evidence Synthesis No. 90. AHRQ Publication No. 12-05160-EF-1. Rockville, MD: Agency for Healthcare Research and Quality; October 2011.
- Chou R, Dana T, Bougatsos C, Fu R, Blazina I, Gleitsmann K, Rugge JB. Treatments for Localized Prostate Cancer: Systematic Review to Update the 2002 U.S. Preventive Services Task Force Recommendation. Evidence Synthesis No. 91. AHRQ Publication No. 12-05161-EF-1. Rockville, MD: Agency for Healthcare Research and Quality; October 2011.

Electronic copies: Available from [U.S. Preventive Services Task Force \(USPSTF\) Web site](#) .

Background Articles:

- Barton M et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. *Ann Intern Med*. 2007;147:123-127.
- Guirgis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. *Ann Intern Med*. 2007;147:117-122. [2 references]
- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med*. 2007;147:871-875. [5 references].

Electronic copies: Available from [USPSTF Web site](#) .

The following is also available:

- Screening for prostate cancer: clinical summary of U.S. Preventive Services Task Force recommendation. 2012. Available from the [USPSTF Web site](#) .
- The guide to clinical preventive services, 2010-2011. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2010. 292 p. Electronic copies available from the [AHRQ Web site](#) .
- Author insight video. Screening for Prostate Cancer: U.S. Preventive Services Task Force recommendation statement. 2012. Available from the [Annals of Internal Medicine Web site](#) .

The [Electronic Preventive Services Selector \(ePSS\)](#) , available as a PDA application and a web-based tool, is a quick hands-on tool designed to help primary care clinicians identify the screening, counseling, and preventive medication services that are appropriate for their patients. It is based on current recommendations of the USPSTF and can be searched by specific patient characteristics such as age, sex, and selected behavioral risk factors.

Patient Resources

The following are available:

- Summaries for patients. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2012. Available from the [Annals of Internal Medicine Web site](#) .
- U.S. Preventive Services Task Force. Understanding Task Force recommendations: screening for prostate cancer. Consumer fact sheet. 2012 May. 3 p. Electronic copies: Available from the [U.S. Preventive Services Task Force Web site](#) .
- Men: stay healthy at any age. Your checklist for health. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 07-IP006-A. February 2007. Electronic copies: Available from the [AHRQ Web site](#) . See the related QualityTool summary on the [Health Care Innovations Exchange Web site](#) .

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to <http://www.ahrq.gov/research/publications/index.html> or call 1-800-358-9295 (U.S. only).

Myhealthfinder is a new tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at www.healthfinder.gov .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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